

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

THIS PAGE BLANK (USPTO)



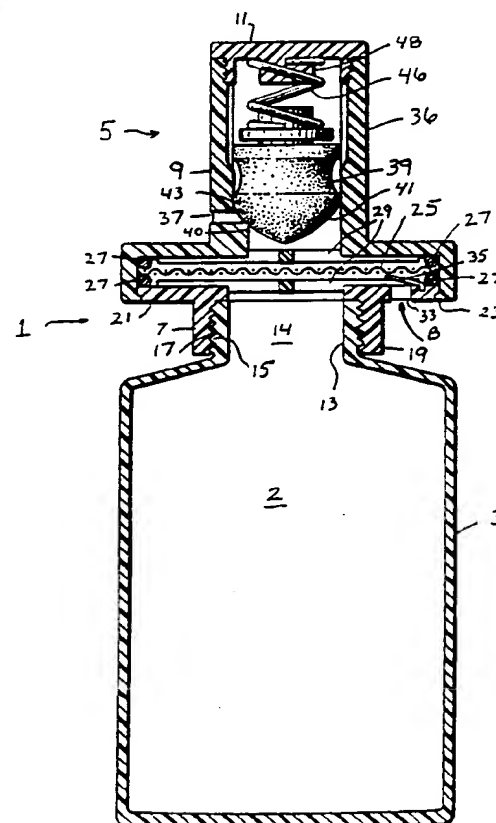
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61J 1/00, A61L 2/02		(11) International Publication Number: WO 92/04004
A1		(43) International Publication Date: 19 March 1992 (19.03.92)
(21) International Application Number: PCT/CA91/00056 (22) International Filing Date: 22 February 1991 (22.02.91) (30) Priority data: 2,025,105 11 September 1990 (11.09.90) CA (71)(72) Applicant and Inventor: WEBB, Garth, T. [CA/CA]; 31521 Brookside Avenue, Clearbrook, British Columbia V2S 6A9 (CA). (74) Agent: GREEN, Bruce, M.; Barrigar & Oyen, 480-601 West Cordova Street, Vancouver, British Columbia V6B 1G1 (CA).		(81) Designated States: AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH (European patent), CM (OAPI patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GA (OAPI patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL (European patent), NO, PL, RO, SD, SE (European patent), SN (OAPI patent), SU ⁺ , TD (OAPI patent), TG (OAPI patent), US. Published <i>With international search report.</i>

(54) Title: DEVICE FOR STORING AND DISPENSING STERILE LIQUIDS

(57) Abstract

Various means are used to produce and dispense sterile saline for use by contact lens wearers. The present invention provides a simple, portable device for storing and dispensing sterile saline which comprises a resilient hollow container having a first outlet, a housing removably mounted on said container and having a second outlet and a passage communicating between said first and second outlet, a liquid-sterilizing filter mounted in said housing in said passage, and valve means for alternately opening and closing said second outlet, whereby pressure applied to said container forces a liquid stored in said container through said filter and out said second outlet when said valve is in an open position.



+ DESIGNATIONS OF "SU"

Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU ⁺	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		

SUMMARY OF THE INVENTION

-2-

5 The present invention provides a simple, portable device for storing and dispensing sterile saline which comprises a resilient hollow container having a first outlet, a housing removably mounted on said container and having a second outlet and a passage communicating between said first and second outlet, a liquid-sterilizing filter mounted in said housing in said passage, and valve means for alternately opening and closing
10 said second outlet, whereby pressure applied to said container forces a liquid stored in said container through said filter and out said second outlet when said valve is in an open position.

BRIEF DESCRIPTION OF THE DRAWINGS

15 In drawings which illustrate a preferred embodiment of the invention:

20 Fig. 1 is a vertical cross-sectional view of the invention with the valve in the closed position;

Fig. 2 is a detail of the view of invention shown in Figure 1, but with the valve in the open position;

Fig. 3 is a horizontal cross-sectional view of the invention taken along lines 3-3 of Figure 2;

25 Fig. 4 is a horizontal cross-sectional view of the invention taken along lines 4-4 of Figure 2;

Fig. 5 is a detail of a second embodiment of the invention in vertical cross-section; and

DEVICE FOR STORING AND DISPENSING STERILE LIQUIDSBACKGROUND OF THE INVENTION

5 The invention relates to the field of devices for sterilizing liquids, and more particularly to devices for storing and sterilizing saline for ophthalmic purposes, and particularly for contact lens applications.

10 Sterile saline is required by contact lens wearers for use as a rinse solution, for rinsing the lens prior to inserting the lens in the eye, and also for soaking the lens during the cleaning and disinfecting process.

15 Sterilization of the saline is generally accomplished using heat, ultra-violet light, or filtration. The saline which has been sterilized in bulk is then stored in plastic squeeze bottles with the addition of chemicals to preserve the sterility. Sterilized saline has also been marketed in aerosol cans, which provide sterile storage without the need for chemical agents. This is accomplished due to the positive pressure within the
20 container which keeps contaminants out. However, the expense and environmental problems associated with aerosol containers make this a less desirable alternative.

25 There is therefore a need for a simple and portable device for storing and dispensing sterile saline.

-4-

supported by two plastic inserts 29 located above and below the filter body and having radial arms 30 such that the radius of insert 29 is slightly less than that of filter 25. Inserts 29 could also form part of base 7 and body 9.

5 A valve 31 is provided in base 7 to permit air to enter container 3 after liquid is expelled. It consists of a small opening 33 and a pivoting, inwardly opening flap 35 on the interior surface of flange 21, shown in an open position in Figure 1 and a closed position in Figure 2. When the container
10 3 is squeezed to expel liquid, flap 35 closes opening 33, and when pressure on container 3 is released, flap 35 opens to allow air to enter container 3 in the direction of arrow B, and to allow container 3 to return to its original volume. The same function could be achieved by a plurality of smaller openings.
15 Alternatively, an accordion type of container could replace a squeeze bottle for container 3 which would obviate the necessity for valve 31.

Housing 9 has a hollow cylindrical portion 36 which forms a lower opening 38 and is provided with outlet port 37.
20 Opening 38 is circular but for shoulder 40 which extends into opening 38. Port 37 is alternately opened or closed by rubber valve 39. Valve 39 has a sloping, rounded lower face 41 which ends in a circular lip 43 which seals against the interior surface of cylinder 36. Shoulder 40 has a sloping upper surface
25 44 which conforms to face 41 to seal port 37 when the valve 39 is in the lower position.

Valve 39 is biased to its lower, closed position by spring 46, one end of which is held on cylindrical base 48

-3-

Fig. 6 is a third embodiment of the invention with the filter housing partially removed from the storage container and shown in vertical cross-section.

5 DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring to Figure 1, the device of the invention is designated generally as 1. It consists of a resilient squeeze bottle container 3 having hollow interior 2, and a valve and
10 filter housing 5. The squeeze bottle portion 3 is manufactured of a flexible plastic such as a polyethylene or PET, which has sufficient resiliency and memory to return to its original shape after being squeezed. The housing 5 is constructed of a rigid plastic such as a polycarbonate. The housing comprises a base 7,
15 body 9 and cover 11. Container 3 has a circular neck 13 forming open mouth 14 and provided with screw threads 15 on its exterior surface which mate with complementary screw threads 17 on the interior surface of circular extension 19 of base 7. Base 7 has a circular flange 21 which has a snap fit connection with
20 circular lip 23 of body 9.

Mounted in the valve and filter housing 5 between base 7 and body 9 is a circular micro-filter 25. Filter 25 is chosen with a mesh sufficiently fine to be useful for the sterilizing function of the invention. A filter having a .2 micron rating is
25 suitable. Such filters are manufactured by Pall Ultrafine Filtration Corporation under the trade-mark ULTIPOR. The filter 25 is sealed in place between base 7 and body 9 by two rubber O-rings 27. To provide rigidity to the filter 25, it is also

-6-

70 is screwed tightly against the lower interior surface of valve 74 by rotation of knob 64. In this embodiment, valve 74 could be replaced by a rubber diaphragm stretched across the interior chamber 88 of body 9, and adapted to seal against outlet 82 when pressure is released and open outlet 82 when pressure is applied. In this variation, shoulder 80 would be generally perpendicular to the walls of chamber 88. Also, to improve the flexibility of valve 74, holes could be provided in disk 68 to permit air to flow between the interior 76 of the valve and the atmosphere.

Figure 5 also shows a second embodiment of base 7 in which the cylindrical flange 19 of base 7 screws into the interior surface of neck 13 of container 3, and a centrally located shield 84 attached to base 7 guards the filter against damage when the container 3 is removed from housing 9. Passageways 86 permit passage of the liquid around shield 84.

Figure 6 illustrates a third embodiment of the invention. In this embodiment, the hollow storage container 90 need not be squeezable, as a plunger 91 is used to provide pressure to the liquid saline 92 to force it through a sterilizing filter 93. The filter housing 94, again constructed of a rigid polycarbonate plastic, has an internally threaded neck 95 which screws onto externally threaded neck 96 of container 90. A hollow feed tube 97 having a lower open end 98 is secured in end piece 105 of housing 94 and extends into container 90 so that end 98 is adjacent the bottom of container 90 when neck 95 is screwed down completely onto neck 96. Tube 97 has an upper open end 99 which opens into a cylindrical chamber 100 formed in end piece 105. Cylindrical wall 101 extends upwardly from neck 95 and

-5-

attached to cover 11, and the other end of which is held on a cylindrical extension 50 of base 52 of valve 39. Cover 11 is screwed into housing 9 by screw threads 51. This permits cover 11 to be removed leaving valve 39 in place. Alternatively, cover 11 can be permanently fixed by an adhesive.

In operation, the hollow interior 2 of container 3 is filled with non-sterile saline and valve and filter housing 9 is then screwed into place. In a rest position, valve 39 closes port 37 due to the action of spring 45. When the user squeezes container 3, flap 35 closes and saline is forced through filter 25 in the direction of arrow A, thereby sterilizing it. Valve 39 moves upwardly opening port 37 and the sterile saline is dispensed from port 37 in the direction of arrow C. When pressure on container 3 is released, valve 39 returns to its closed position, closing port 37, and flap 35 opens to permit air to enter to return container 3 to its original shape.

A second embodiment shown in Figure 5 permits valve 39 to be locked in a closed position for transport. In this embodiment cover 11 in turn is provided with opening 60 provided with screw threads 62 into which a knob 64 is screwed by screw threads 66 on disk 68. Attached to the lower surface 69 of disk 68 is a rod 70 with bulbous lower end 72. Rubber valve 74 has a hollow interior 76 into which rod 70 extends, and a flat lower face 78 which seats against shoulder 80 of outlet port 82. Valve 74 is sufficiently resilient in this embodiment, due to the flexing action of its walls, to open and close outlet port 82 in response to the squeezing of container 3 when rod 70 is withdrawn. However valve 74 is locked against opening when rod

-8-

Passage 116 runs from chamber 112 to circular chamber 117 which is covered by a circular rubber membrane or diaphragm 118. Diaphragm 118 is secured at its outer edge by clamp piece 121 and is stretched across central cylindrical extension 119 through the centre of which runs passage 120 to the exterior of the housing. Cap 122 can snap over shoulder 123 to cover the open end of passageway 120.

Plunger 91 consists of a hollow cylinder 130, one end of which is closed by cap 132. Spring 134 sits at one end in a circular groove 135 and the opposite end sits in the hollow cylindrical central channel of plunger 138. Plunger 138 slides through aperture 139, and has attached at one end thereof a flexible plastic piston 136 which slides in cylinder 130. Passageway 142 extends from chamber 144 within cylinder 130 to chamber 109. Spring 134, which biases the plunger outwardly, is optional. Plunger 138 could be made with a solid shaft. Alternatively, spring-operated plunger 138 could be replaced with an accordion-like plunger which was also biased outwardly.

In operation, withdrawal of plunger 138 creates a vacuum within chambers 144 and 109. The greater air pressure in container 90 than in chamber 109 therefore causes saline 92 to move up feed tube 97 into chamber 100, through passage 150, around filter 107, filling chamber 109 and 144. Plunger 138 is then pressed inwardly to force filter 107 against support 106, closing aperture 148. Saline from chamber 109 is then forced through filter 93, causing it to be sterilized. Pressure on diaphragm 118 opens passageway 120 permitting the sterilized saline to be dispensed out of passageway 120. Filter 104 permits

-7-

has an aperture 102 which communicates with the interior of chamber 100 by way of passage 103. Passage 103 is covered by a hydrophobic filter 104 which thus permits air to travel through it, but not water or other liquids. Air passing through filter 104 is sterilized. A flap valve could also function in replacement of filter 104 to permit air to enter chamber 100 from the exterior of the container while preventing liquid from escaping.

A filter support 106 supports hydrophobic filter 107 which is circular in shape and is free to slide upwardly in cylindrical chamber 109. Filter support 106 is a plastic disc with a central opening 148 extending from chamber 100 to chamber 109. Filter 107 has a diameter large enough to completely cover opening 148 when the filter is in the lower position. Liquid or air is able to flow through opening 148 and around filter 107 into chamber 109 when filter 107 is raised up off support 106. Filter 107 functions therefore much like flap valve 35 in Figure 5. Filter 107 could also, for example, be held in a circular frame which guides it against the sides of chamber 109, but permits the flow of liquid between the filter 107 and the walls of chamber 109.

Passageway 110 extends upwardly in housing 94 from chamber 109, with its upper end covered by hydrophillic filter 93. Filter 93 is held in place by O-rings 115. Filter support 111 is a perforated plastic disk which sits in a cylindrical chamber 112 formed between upper housing piece or filter head 113 and lower housing piece 114. O-ring 115 seals the junction of piece 114 and filter 93. In this way liquid flowing up passageway 110 is forced through filter 93 rather than going around its edges.

-10-

CLAIMS:

1. A device for storing and dispensing a sterile liquid comprising:

5 a) a housing
 b) a hollow chamber for receiving said liquid and having a first outlet;
 c) said housing having a second outlet and a passage communicating between said first and second outlets;

10 c) a liquid-sterilizing filter mounted in said housing in said passage; and

 d) first valve means for alternately opening and closing said second outlet;

15 whereby pressure applied to the interior of said chamber forces said liquid stored in said chamber through said filter and out said second outlet when said valve is in an open position.

20 2. The device of claim 1 wherein said chamber comprises an expandable and contractible container having a hollow interior, and said housing is mounted on said container.

25 3. The device of claim 2 wherein said expandable container is adapted to be contracted by squeezing by the hands of a user.

 4. The device of claims 2 or 3 wherein said container comprises air inlet means communicating between said hollow interior of said container and the exterior of said container, said air inlet

-9-

sterilized air to enter the feed tube to replace the ejected saline. Air passing back through filter 107 into the feed tube will also be sterilized. The feed tube 97 is also optional. If it were removed, tilting of the container 90 would be required to place saline in chamber 109.

As will be apparent to those skilled in the art, various modifications and adaptations of the structure above described may be made without departing from the spirit of the invention, the scope of which is to be construed in accordance with the accompanying claims.

-12-

11. The device of claim 10 wherein said filter extends completely across said passage.

12. The device of claim 1 wherein said container is a plastic squeeze bottle.

13. The device of claim 12 wherein said first outlet is circular and said housing is mounted on said container by screw threads.

14. The device of claim 1 further comprising means for applying pressure to the interior of said container.

15. The device of claim 14 wherein said means for applying pressure to the interior of said chamber comprises a piston movable within a cylinder, said cylinder having an open end communicating with said interior of said chamber.

16. The device of claim 15 further comprising a hollow storage container having an outlet communicating with said chamber.

17. The device of claim 16 further comprising valve means between said container and said chamber adapted to prevent the flow of liquid in a direction from said chamber to said container.

18. The device of claim 16 further comprising valve means adapted to permit the flow of air from the exterior of said container to the interior of said container but preventing the flow of liquid

means further comprising second⁻¹¹⁻ one-way valve means adapted to permit flow of air into said container but preventing flow of air out of said container through said valve.

5 5. The device of claim 1 wherein said first valve means comprises a resilient sealing surface biased in a direction to seal against said second outlet and adapted to be movable to open said second outlet upon application of pressure against said surface.

10

6. The device of claim 1 wherein said filter has a mesh having rating of .2 microns or less.

15 7. The device of claim 1 wherein said housing comprises a hollow cylindrical chamber, and said first valve means is mounted for reciprocal motion in said chamber.

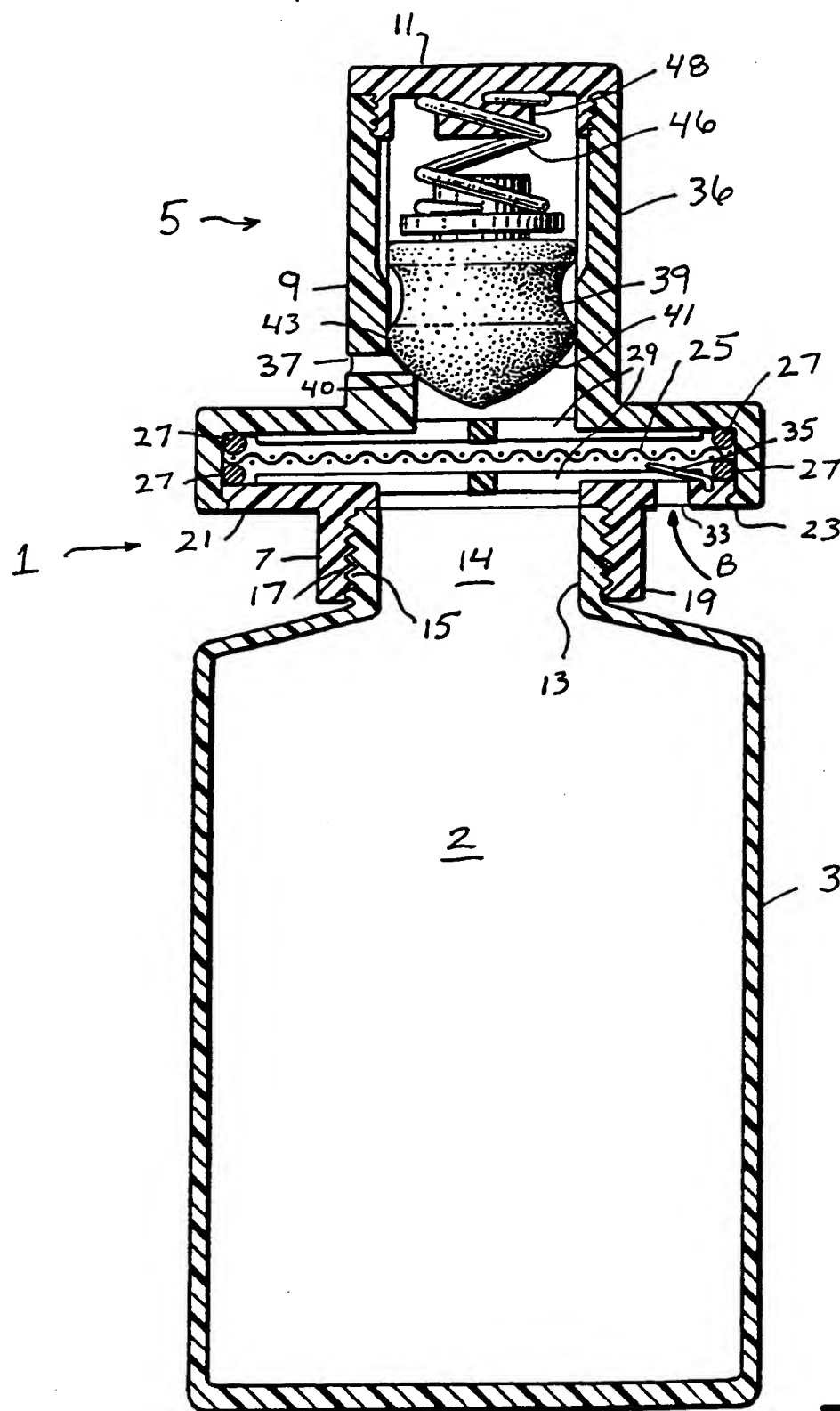
8. The device of claim 7 wherein said first valve is biased by means of a spring mounted in said chamber.

20

9. The device of claim 1 wherein said housing is mounted coaxially on said container and said filter is mounted coaxially between said housing and said container.

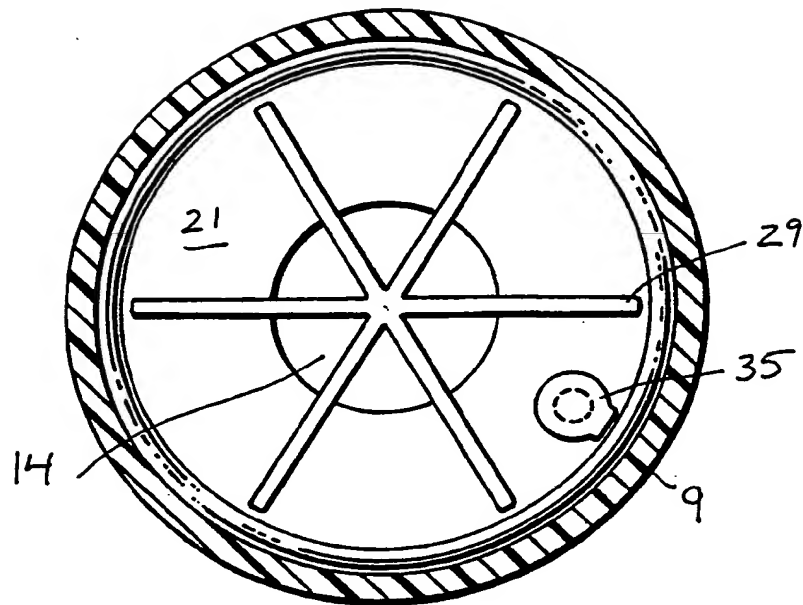
25 10. The device of claim 1 wherein said filter extends perpendicularly to the direction of fluid flow in said passage.

1/5



from the interior of said container⁻¹³⁻ to the exterior of said container.

5 19. The device of claim 16 further comprising valve means between said chamber and said storage container preventing the flow of liquid from said chamber to said storage container when pressure is applied to the interior of said chamber.

FIG. 4

5/5

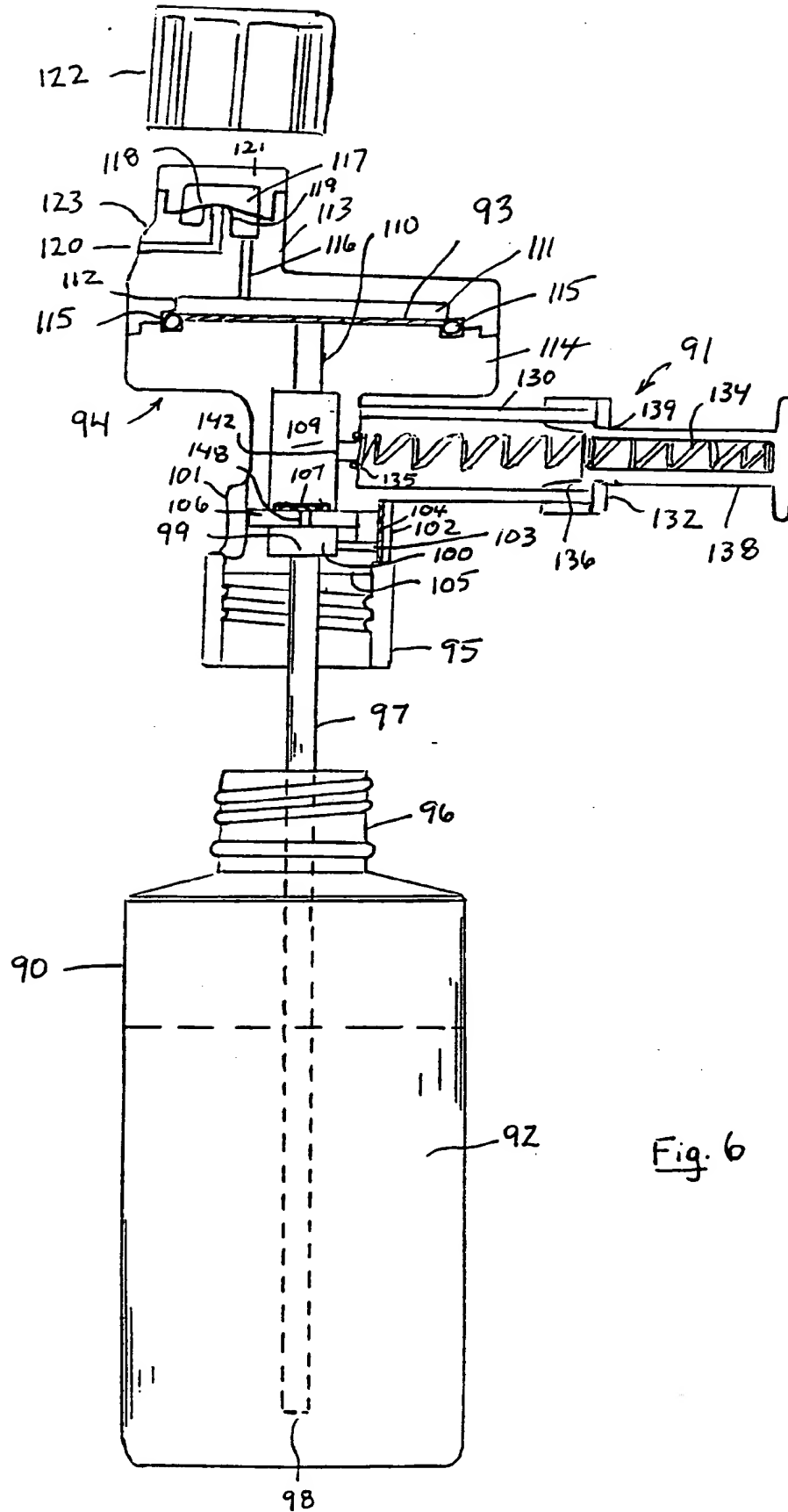


Fig. 6

4/5

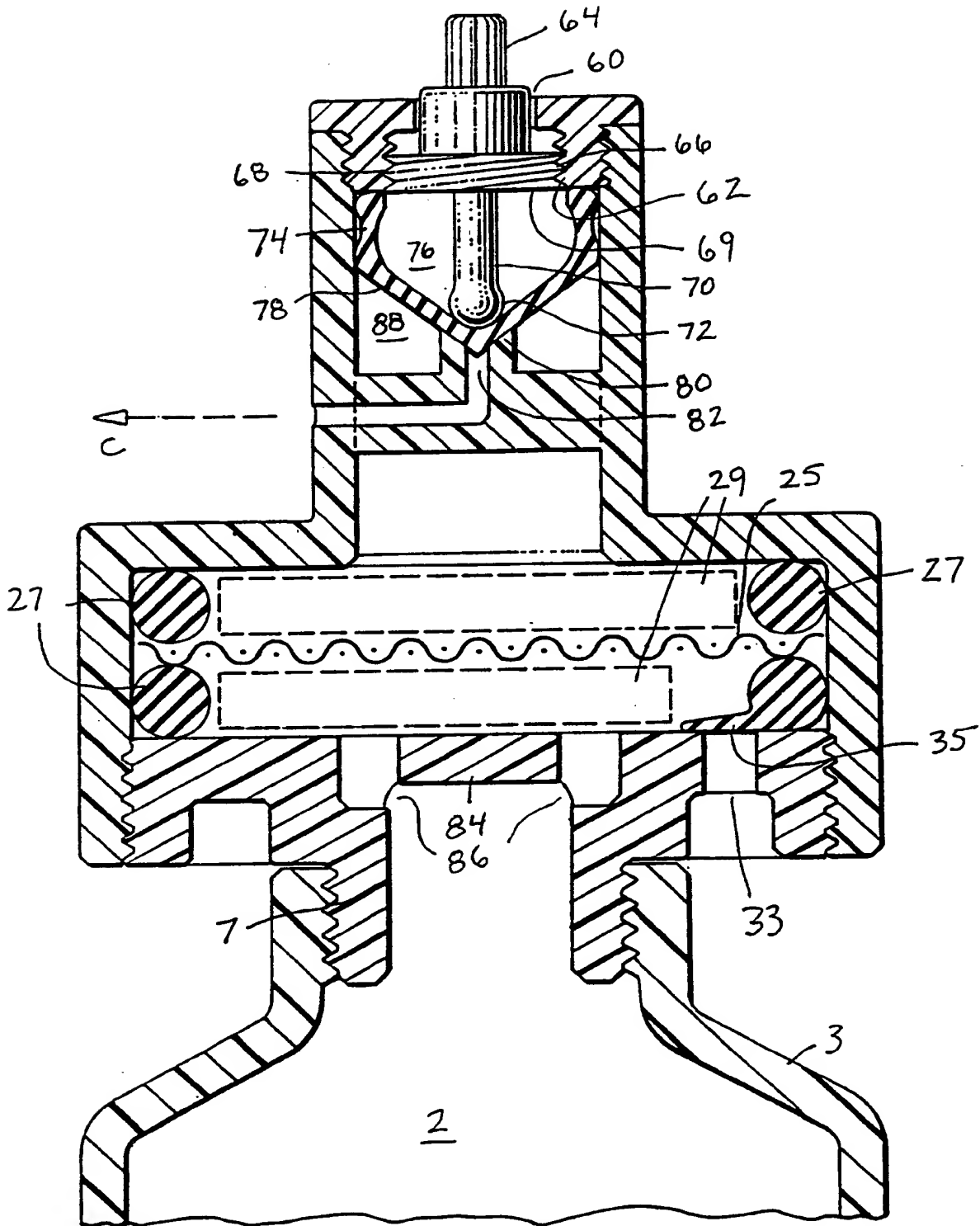


FIG. 5

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

CA 9100056

SA 44720

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

21/06/91

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A-1000248		None	
GB-A-2106877	20-04-83	US-A- 4533068	06-08-85
		AU-A- 8719482	31-03-83
		BE-A- 894113	01-12-82
		DE-A- 3230310	19-05-83
		FR-A- 2511242	18-02-83
		JP-A- 58078661	12-05-83
		LU-A- 84334	23-03-84
		NL-A- 8203187	16-03-83
		SE-A- 8204678	13-08-82
EP-A-0363172	11-04-90	AU-A- 4260489	12-04-90
		JP-A- 2180659	13-07-90
DE-A-3628197	25-02-88	None	
DE-A-3146343	20-10-83	None	
FR-A-2422569	09-11-79	GB-A, B 2021429	05-12-79
US-A-4463880	07-08-84	None	
US-A-3149758		None	

EPO FORM P0479

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

INTERNATIONAL SEARCH REPORT

PCT/CA 91/00056

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61J1/00 ; A61L2/02		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61J ; A61L	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	GB,A,1000248 (R.C. CRISAFI) 04 August 1965 see page 1, lines 72 - 74; claims 1-3 ---	1-14
Y	GB,A,2106877 (E. MEIERHOEFER) 20 April 1983 see claims 1-32 ---	1-14
A	EP,A,0363172 (RYDER) 11 April 1990 see claim 2 ---	1
A	DE,A,3628197 (H. STREITENBERG) 25 February 1988 ---	
A	DE,A,3146343 (PROAQUA-PROVITA) 20 October 1983 ---	
A	FR,A,2422569 (ROUSSEL-UCLAF) 09 November 1979 ---	
A	US,A,4463880 (S.G. KRAMER) 07 August 1984 ---	
A	US,A,3149758 (J.H. BUSH) 22 September 1964 ---	
<p>¹⁰ Special categories of cited documents : ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
22 MAY 1991	12 JUL 1991	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	MISS T. TAZELAAR	

Form PCT/ISA/210 (second sheet) (January 1985)